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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,747	01/10/2005	Masahiko Koike	084437-0174	3250

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EXAMINER

PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,747	Applicant(s) KOIKE ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 18 July 2008. The Examiner acknowledges the following:

Claims 3 and 9 as well as non-elected claims 2, 11 and 12 are acknowledged by the Examiner as having been cancelled.

Claims 1, 4-8 and 10 have all been amended. Where support for the amendments was not expressly provided, it was found either within Applicants' disclosure and/or originally filed claims. For example the limitations amended into claim 1 derive their support from cancelled claims 3 and 9.

The Examiner acknowledges that no new matter has been added to the claims.

No claims have been added.

Thus, claims 1, 4-8 and 10 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to both the Abstract and Title of the Invention renders moot their objection. Thus, said objections have been **withdrawn**.

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Rejection under 35 USC 112

Applicants' amendments removing the phrase, "solid solution" from claim 1, and clarifying the language regarding the second drug in claim 2, render moot the rejections to claims 1 and 2, under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' amendments to the instant claims, namely claims 1 and 10, render moot the rejection to claims 1 and 3-10 under 35 USC 102(b) as being anticipated by Timmins et al. (USPN 6,031,004). Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 22 February 2008:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (U.S. Patent 6,031,004) in view of Cutie et al. (WO 91/82875).

The instant claims are drawn to a method of producing a coated preparation that comprises a coating dispersed with pioglitazone hydrochloride in an organic solvent as well as a coating base which is soluble in said organic solvent, as described above. Dependent claim 8 further defines the organic solvent of claim 1 as ethanol and claim 9 further limits the “coating base soluble in organic solvents” to polyvinylpyrrolidone (PVP).

Timmins et al. teaches the preparation of coated formulations of metformin salts (Examples –10, col. 2, lines 26-33), where the tablet cores also include a coating layer which further one or more film-formers or binders (col. 5, lines 38-43). Binders taught include polyvinylpyrrolidone (col. 5, lines 15-17). The film formers of the coating are taught to be applied from a solvent system containing one or more solvent such as ethyl alcohol (col. 5, lines 53-55). Timmins also teaches that the thiazolidinedione oral anti-diabetic agent pioglitazone is employed in combination with the metformin salt (col. 3, lines 59-64). However, pioglitazone is not expressly taught as a coating or as being dispersed within the coating of the dosage.

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Cutie et al. teaches a method for producing a combined formulation of pioglitazone and metformin, as described above, wherein pioglitazone is taught to be deposited on at least a portion of a surface of the core.

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to shift the position of the pioglitazone hydrochloride within the composition from being generally combined with metformin salts, as practiced by Timmins et al., to being dispersed within the coating that surrounds the metformin salt core, as practiced by Cutie et al. with a reasonable expectation of manufacturing a coated dosage form capable of delivering dual anti-diabetic active ingredients to diabetes patients. Such would have been obvious in the absence of evidence to the contrary because Cutie et al. teach that the creation of a formulation where both medicaments create a synergistic effect with one another to manage diabetes (pg. 1, lines 16-19). It is also taught that variation in the resulting coated core formulation may serve to alter the release profile of the dosage, thus extending the time period of a patient's single dosage treatment.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 4-8 and 10 under 103 over Timmins in view of Cutie et al. have been fully considered but they are not persuasive.

Applicant argues that Timmins "does not disclose polyvinylpyrrolidone used as a base in an organic solvent coating", that "Cutie does not teach at all the dissolution property of pioglitazone hydrochloride" and that neither Timmins nor Cutie suggest such a property.

First, in response, the Examiner agrees with Applicants on the point that Timmins

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does not disclose polyvinylpyrrolidone (PVP) as a base in an organic solvent. However, the Examiner respectfully submits that Applicants' instant claims 1 and 10, as amended, do not clearly recite the inclusion of PVP as a part of the coating composition. The instantly amended claims recite a method for producing a coated preparation, which comprises an active agent-loaded core with a dispersion of pioglitazone hydrochloride in an organic solvent, and which contains PVP. Applicants have not clearly recited which part of the composition comprises PVP: the core or the coating. Thus, given their broadest reasonable interpretations, claims 1 and 10 are interpreted by the Examiner as now reciting the presence of PVP anywhere within the composition. Given the amendment and the Examiner's interpretation thereof, the combined teachings of Timmins and Cutie continue to read on the rejected claims.

Secondly, in response to Applicants' arguments that the references fail to address certain features of Applicants' invention, it is noted that the features upon which Applicants rely (i.e., dissolution properties) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, had the rejected claims contained limitations reciting dissolution properties of pioglitazone, said limitations would have been read upon by any teaching of the composition, absent any distinguishing evidence to the contrary. Thus, as Applicants have provided no such evidence and the above rejection teaches and suggests the method for producing the pioglitazone-coated composition, said properties are considered as having been taught as well.

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For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained.

All claims still under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615